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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,731	05/17/2006	Kazumichi Uotani	0171-1273PUS1	8869
2292 7590 03/23/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER YOUNG, HUGH PARKER	
			ART UNIT	PAPER NUMBER
			1654	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		03/23/2007	ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/23/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

**Office Action Summary**

Application No.

10/579,731

Applicant(s)

UOTANI ET AL.

Examiner

Hugh P. Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date May 17, 2006.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

This is the first Office action on the merits of application No. 10,579,731. There are eight claims pending, all of which are presently under consideration.

#### ***Objections to the specification***

1. The disclosure is objected to because of the following informalities: The claim of benefit to a foreign priority is not clearly stated in the first line of the specification.

Applicant does provide two cover pages to the specification that state that "the attached" is an official translation of a PCT application, PCT/JP2004/0173238, but any claim to priority under 35 USC § 371 must be properly and explicitly made in the first sentence of the specification. Applicant does recite the PCT and original national application data in the oath and affirmation and has provided a copy of the official priority document as part of the national stage application, but the statement of continuity information itself must be made in the specification proper, as above.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 1-3 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by M. R. Johnson, in US Patent Application Publication 2003/0195160 A1, published October 16, 2003 (filed February 19, 2002).

3. Johnson teaches a compound that is a sodium channel blocker directed, among other purposes, to modulating sodium channels so as to allow proper moisturizing or wetting of mucosal surfaces (paragraphs [0004-0005], page 1), reciting xerostomia in particular (paragraph [0011], page 2) as one particular problem related to lack of surface liquid and that one object of his invention is to provide a method of treating dry mouth xerostomia comprising administering to the mouth of the subject the compound of his invention (paragraphs [0092-0093], page 4), which can be formulated as a salt of organic acids such as polyglutamic acid (paragraph [0162], bottom right-hand column of page 5, the recitation of polyglutamic acid itself being in the first line of the left-hand column of page 6). The method of treating dry mouth (xerostomia) by administering the compound (or its salt) is claimed in claim 65, left-hand column, page 22. It can be appreciated that although Johnson does not claim polyglutamic acid in his claim regarding his method of treating xerostomia, his inclusion of polyglutamic acid in a list of art-recognized pharmaceutical salt components teaches the use of polyglutamic acid or its salt form, polyglutamate, as part of a treatment for xerostomia. It being in the nature of salts to readily dissociate into their component species it can be further appreciated that polyglutamate ion would thus be able to exert any expectorant or sialogenic effect in may possess. Johnson's method of administering the active salts is not claimed but is suitable to the location being treated, as per the mouth if necessary.; similarly Johnson's

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claims are directed to "an effective amount" of his compound without any limitation as to the range of concentrations embodied. It should be noted that M. R. Johnson has a similar invention, disclosed in US Patent Application Publication 2003/0199456 A1, published October 23, 2003 (also filed February 19, 2002), relating to a similar sodium-channel blocker, formulated similarly, to be used in methods of treating similar mucosal hydration conditions, including xerostomia, as above.

4. Claims 1-3 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanimoto et al, in US Patent 5,447,732, issued September 5, 1995 (filed October 7, 1994).

5. Tanimoto et al teach a composition containing poly- $\gamma$ -glutamic acid and its degradation products that will act as a mineral-absorption enhancer when used in foods, in a variety of forms, including beverages, gels, solids or powders. Tanimoto et al. also teach that poly- $\gamma$ -glutamic acid is naturally available in a non-isolated product of the bacterium *Bacillus natto*, and that the advantage of Tanimoto et al's invention is that poly- $\gamma$ -glutamic acid can be provided as a source of nutrition, in pure form, with less cost and labor (column 3, lines 52-68). Tanimoto et al also teach that poly- $\gamma$ -glutamic acid and its sodium or other salts can be used interchangeably (column 4, lines 60-62) and that it can be readily used as or in food (column 4, lines 63-69, carried over to column 5, lines 1-52). In this regard Tanimoto et al further provide a recipe for beef curry in which sodium poly- $\gamma$ -glutamate is used as an ingredient (column 10, Example 10, lines 34-56, carried over to lines 1-15 of column 11. More food recipes incorporating sodium poly- $\gamma$ -glutamate are provided throughout the remainder of columns 11, 12, and 13. Tanimoto

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et al claim compositions comprising 0.1-10% w/w poly- $\gamma$ -glutamate in claim 1 and similarly, with a concentration of 0.01-5% w/w in their claim 2, this broad range anticipating the instant claim 5 by overlap. It can be appreciated that the incorporation of poly- $\gamma$ -glutamate into food items it can be consumed from one to as many times per day as desired or required, thus anticipating the instant claim 6. Tanimoto et al's claims 5-13 claim use of their composition comprising poly- $\gamma$ -glutamate in a range of food types (liquid, solid or powder) and foodstuffs. The methods of providing the poly- $\gamma$ -glutamate composition to mammals are claimed in claims 14 and 15.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 4-6 rejected under 35 U.S.C. 103(a) as being unpatentable over M. R. Johnson, in US Patent Application Publication 2003/0195160 A1, published October 16, 2003 (filed February 19, 2002).

9. In the instant case, Johnson, in paragraph [0162], pages 7-8, lists compounds that are suitable for preparing salts of his active ingredient for a preparation directed towards alleviating xerostomia. Johnson's active ingredient, a sodium channel blocker, acts on ion channels and can be administered in its pure form or conjugated and organic acid and presented to the subject as a salt. One suitable organic acid stated by Johnson is polyglutamic acid (page 8, left-hand column, line 1). Polyglutamic acid is a member of a list of incidental ingredients of Johnson's invention and it would be obvious to select through the list and use polyglutamic acid in a formulation to be used for the same intended result, namely, improved flow of saliva and alleviation of xerostomia.

### ***Conclusion***

10. No claims are allowed. The instant claim limitations are anticipated by the prior art as taught or claimed in US Patent documents, as above. The use of polyglutamic acid and polyglutamate salts are well known in the food and pharmaceutical industries, and the materials are used both as intentional sialogogue and as more broadly directed components of foodstuffs and medicaments.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

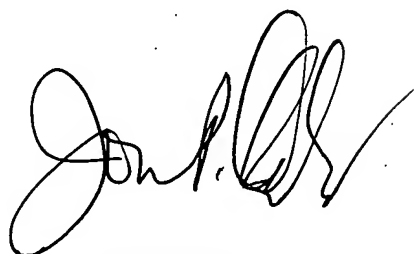
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hugh P. Young Ph.D.

GAU 1654



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**